7 September 2004

UNICE RESPONSE TO COMMISSION QUESTIONNAIRE*

WORKING GROUP ON PRODUCT LIABILITY

A. THE LOVELLS' STUDY: "PRODUCT LIABILITY IN THE EUROPEAN UNION"

1. Difference in the success rate of product liability claims in different Member States.

The study has shown that this difference is attributable to a number of factors, ranging from differing procedural rules to discrepancies in the interpretation of the relevant provisions of the Directive, from different assessment of damages to variations in consumers' attitudes towards product liability claims.

- **Can the members provide additional information on this finding?**

UNICE answer:

The experience of product liability claims in the EU is still limited, and it is difficult to draw general conclusions about the relative success rates of product liability claims under different national systems.

The limited experience of product liability claims is due, in part, to the fact that the safety of consumer products is well regulated in the EU, and as a result consumers generally enjoy a high level of protection from unsafe or defective products throughout the EU. It is also due to a range of cultural and socio-economic factors that were identified in the Lovells Report.

- **Did they experience variations in court decisions from different Member States on broadly similar cases? If this is the case, can they point to any factor which in their view influenced the outcome of the proceedings?**

UNICE answer:

There is some evidence that there are differences in the way the Product Liability Directive is interpreted by the courts in different countries. There is also some evidence that the Product Liability Directive can be subjected to varying interpretations by courts within the same country. For example, in the United Kingdom, the court in *A v National Blood Authority* said that it was not relevant to take into account the conduct of the defendant when assessing whether the product is defective, whereas the court in *Bogle v McDonalds Restaurants* (despite endorsing the decision in *A v National Blood Authority*), considered it was relevant to consider the steps taken by the defendant to minimise the risk.

* See Commission's working document provided to participants in advance of the meeting of 4 June 2004 of the working group on Product Liability.

Differences in interpretation of substantive laws are unlikely to be the most significant factor in determining the success rate of product liability claims. Product liability systems will necessarily operate differently in different member states because, for example, consumers in some member states, for cultural reasons, may be more likely to seek to claim damages when injured by a product. Further, the level of damages awarded to victims of defective products will inevitably vary between member states simply because of differences in social security systems, taxation regimes and legal traditions.

It would be wrong to conclude that such differences in the interpretation of the Directive necessitate substantive changes to the Directive, particularly while there is still relatively little experience of the true practical impact of those differences. We also agree with one of the conclusions in the Lovells' report that over time, the wider experience of the Directive may lead to greater consistency in its application by national courts, especially if the ECJ is called upon to consider some of the matters of controversy.

- **Can they provide evidence that the "optional provisions" of the Directive can play a role in this respect?**

UNICE answer:

There does not seem to be any evidence that the two remaining "optional" provisions are contributing to any significant differences in the success rate of product liability claims in different Member States.

The optional damages cap in Article 16(1) has been implemented by a small number of Member States. There do not appear to have been any cases in which the cap has actually been applied to date. It may well be that as the experience of use of the Product Liability Directive increases, cases will emerge in which the cap does become relevant. On the basis that questions of quantum of damages under the Directive are matters for national law, it would appear to be entirely appropriate to retain the option for Member States to adopt this cap if they consider it desirable under their national systems.

The option under Article 15(1)(b) to exclude the development risks defence in Article 7(e) has been exercised fully by Finland and Luxembourg, and partially by France, Germany and Spain for specific sectors. Although cases in which the defence has been successfully relied upon have been rare to date, there is evidence, as identified in the Fondazione Rosselli Report, that the existence of the defence performs an important function within the overall scheme of the Product Liability Directive.

2. The concept of "defect"

The study emphasizes that the concept of defect is central to the application of the Directive. It is also inextricably linked to the question of the burden of proof: some courts are reported to require that the victim prove the actual cause of the accident, whereas others content themselves with the claimant's proving that the product failed. The study suggests that the concept could be more precisely defined by the Directive itself, in the absence of any guidance from the case law of the European Court of Justice.

- **Do the members know of any recent court case where failure to prove the exact cause of the failure has resulted in the claim being dismissed?**

  UNICE answer:

  There have been claims in various Member States which have failed because the claimant was unable to discharge the burden of proving the defect in the product. In some of those cases, the courts have said that the claimant has to prove the precise nature of the defect. These cases are contrasted with other cases, in which the courts have said it is sufficient (at least in the circumstances of the particular case) for the claimant simply to prove that the product failed and that such failure caused an injury.

  The concept of "defectiveness" is inevitably controversial, and incapable of a precise definition that will provide a ready answer for all circumstances. It is noteworthy that in the United States, where there is a much more extensive experience of product liability claims, the concept of "defect" remains hotly debated, and is constantly evolving.

- **Could they envisage the terms of a more clear-cut definition?**

  UNICE answer:

  We consider that it is right that the claimant should prove the defect, the damage and causation, as specifically provided for in the Directive. Although there is as yet very little evidence from court cases on this point, it is indeed possible that there may be differences in approach to the burden of proof between different courts in different member states. When it seems that sufficient evidence is available, this point should be clarified through a carefully focused research study.

  At this stage, on the basis that there is no strong objective evidence that reform is needed, the best approach is to wait until there is evidence from a broader experience of the Directive before fundamental changes are considered.

On a separate though not unrelated note, it is worth mentioning that in legal literature it is often discussed to what extent the Directive's test implies a 'risk/benefit' analysis, or to what extent courts have surreptitiously employed such a test in the absence of any indication in the Directive.

- **Are the members aware of any clear example of the courts' inclination to make use of a cost/benefit analysis?**

  UNICE answer:

  As for the question about the application of a "cost/benefit" analysis to assess the defectiveness of a product, there are cases of rejection of the cost/benefit approach for instance as it was made by the English High Court in A v National Blood Authority. However, there are examples of cases in which the courts may be regarded as having considered a cost/benefit analysis to be relevant, for example in Bogle v McDonalds in the United Kingdom, where the public's desire for their coffee and tea to be served at a high temperature was an important consideration when assessing whether the hot beverages were "defective".

Can they provide information on the application of such a test to be appropriate in the context of the Directive, ostensibly couched in terms of 'safety expectation'?

UNICE answer:

There is certainly a theoretical question as to the extent to which a "consumer expectations" test such as that which appears in Article 6(1) of the Directive ought to take into account risk/benefit analyses. This is something that is likely to be the subject of further judicial consideration. There is not, at least at this stage, sufficient evidence that the consumer expectations tests need to be reformulated.

3. The 500 EURO threshold

The study refers to a number of calls from consulted parties for reform of this provision. It also points out that the interpretation of this provision varies in different Member States, as it is treated as a deductible in some of them and as a minimum admissibility threshold in some others.

- **Can the members provide information on the impact of the threshold relevant to the need to strike a balance between the interests of the various stakeholders?**

UNICE answer:

In most countries, there is no evidence that the €500 threshold has had a significant impact in discouraging consumers from asserting small claims under the laws implementing the Product Liability Directive. It would be expected that the threshold would have a greater impact in jurisdictions that better accommodate small claims (e.g. through the Consumer Complaints Board in Finland and the National Board for Consumer Complaints in Sweden) than in others, where legal claims can be more expensive to pursue.

The threshold performs a sensible function. The threshold was included in the Directive to ensure that the strict liability regime did not encourage a glut of very low-value claims. It is unclear what the economic impact would be if the threshold was removed.

We are aware, as was analysed some years ago, that some member states have interpreted the provision as a general deductible from all damages, whereas other member states regarded it as a threshold and not a deductible. We believe that the correct interpretation of this provision should be as a general deductible from all damages.

There may be some merit in clarifying the meaning of the threshold - that is, clarifying whether it operates as a deductible or purely as an admissibility threshold, to ensure parity of treatment as between all Member States. This point could be clarified by the Commission issuing some guidance and clarifying the correct meaning in discussion with member states, as an alternative to amending the Directive.

4. A defence of regulatory compliance

The study reports that some participants, notably representatives of the pharmaceutical sector, argued strongly for the introduction of a defence of regulatory compliance, which would apply to a product whose safety was closely regulated.

- **Do the members share this view?**

  UNICE answer:

  UNICE is of the view that there is an increasingly good case for introducing such a defence. There has been enormous expansion in the past 15 years of regulatory law and requirements, applying not just to pharmaceuticals but also to many other industrial product sectors. There are now extensive harmonising Directives dealing with product regulation: although many of these are little known outside the particular industrial sector to which they apply, their effect in setting regulatory requirements and standards is profound. It would be very confusing if, on the one hand, the regulatory authorities and courts dealing with regulatory/criminal enforcement issues, and, on the other hand, courts dealing with civil compensation matters, were to produce conflicting decisions that set differing standards for industrial requirements, levels of safety or levels of consumer protection. Moreover, our experience is that civil courts are generally unfamiliar with regulatory requirements, and that there is a distinct risk that they will approach compensation issues with an inevitable disregard for regulatory issues.

- **Can they provide evidence that a defence of regulatory compliance would be the most suitable tool to achieve this interdependence?**

  UNICE answer:

  It would be an undesirable state of affairs if certain features of a product were subject to, and complied with, safety regulations, but those self same features could lead to the product being condemned as "defective" in a claim brought under the Product Liability Directive. In other words, if mandatory regulations define what is a proper level of safety for a particular aspect of a product, it should not be possible for courts, when dealing with a claim under the Directive, to define a different standard of safety in conflict with the mandatory regulations. If they do so, it would undermine the entire function of the regulatory regime under which the safety regulations have been carefully developed.

  It should be stressed that is *not* being suggested that the mere fact that a product is subject to safety regulations means that the product should be excluded from the application of the Directive - the defence would operate only where necessary to avoid the application of the Directive conflicting with the operation and objectives of the safety regulations.

5. Damages

The determination of recoverable damages is indicated in the study as one of the factors that account for the reported difference in the handling of product liability claim between Member States. Apart from rules governing the assessment of damages, the most important factor in this respect is thought to be the recoverability of non-material damages.

- **Can the members provide further information on this subject?**

- **Do they consider that it should continue to be governed exclusively by national law?**

UNICE answer:

In general terms, questions concerning the assessment of damages ought to be left to national laws. This is because the amount of damages that is appropriate in any given case is a function not only of the nature and seriousness of the injury, but is also dependant on the level of social security benefits, health care costs, taxation regimes, cost of living generally, community standards and legal traditions. All of these factors are very individual to each Member State.

While it may be appropriate for the Product Liability Directive to set some broad parameters for damages (as we see in Article 9), it is not appropriate for greater intervention to be considered.

It is clear that differences in the treatment of damages will give rise to some differences in the operation of product liability systems as between the Member States. However, we consider that this is not an area in which the EU should intervene.

- **What in their view is the impact of the availability of non-material damage on the number of product liability claims?**

6. Access to justice and procedural rules

The study highlights the influence of rules of procedure on the level of product liability risk, which is also clearly illustrated by the comparison with the U.S. system. The availability of group action is perhaps the single most influential factor in this respect.

- **Can the members of the group provide information on the existing EU initiatives in this field and if these are bringing about a more uniform procedural environment?**

- **What are the options to strengthen and extend to new areas (such as group actions)?**

UNICE answer:

As the Lovells report identified, access to justice and procedural rules play a central role in the operation of product liability systems. These factors are therefore responsible for many of the differences that exist between Member States in the way in which the Product Liability Directive operates, and the impact it has in particular Member States.

Procedural rules, and issues of access to justice are invariably the product of long-standing legal traditions, as well as social and economic factors at a national level. These factors find their own balance in any Member State. Differences between Member States do not necessarily mean that the provisions in any particular Member State are too weak or narrow. In our opinion, there is no solid evidence that there is any pressing need to "strengthen" and "extend" areas of access to justice.

In particular, any suggestion that areas such as "group actions" ought to be dealt with at a Community level need to be treated with extreme caution. The perils of group action procedures are well demonstrated in the United States, and it is noteworthy that the trend in the United States is now to narrow the scope of class actions in the context of product liability rather than expand them.

B. THE ROSSELLI STUDY: "ANALYSIS OF THE ECONOMIC IMPACT OF THE DEVELOPMENT RISK CLAUSE"

1. Development risk clause and insurance/insurability

The conclusions of the study state that the development risk clause, though rarely applied in court proceedings, is perceived by all stakeholders as a crucial means to strike an appropriate balance between the competing values of promoting innovation and ensuring the requisite product safety and just compensation in case of accidents. The removal of the clause is thought likely to produce soaring insurance costs and even the lack of adequate insurance for large risks.

- **What additional information can the members provide on this matter?**

UNICE answer:

UNICE fully supports the justification for the "development risks" defence that is to provide a balance overall as between the interests of consumers, industry and even the state in sharing risks and the financial consequences for injury caused by products. The balance struck by the "development risks" defence is between providing compensation for damage and not stifling innovation. That justification is still just as valid today.

While it is clear that the development risk clause has rarely been successfully relied upon in claims to date, it is evident that the industry, including insurers, places great significance on its existence.

It follows from that fact alone that there is a real risk of increasing insurance costs, and possible non-insurability if the defence is removed. Besides, this removal will fundamentally upset the overall balance of the directive.

This is an issue of even greater concern to industries that are typically involved in developing innovative products.

2. Development risk clause and innovation

The study also suggests that at all events the link between development and the rate of product innovation is too complex to be summarised in a simple formula of direct dependence. In particular, the authors of the study surmise that "strict liability regimes would induce greater process innovation, an increased rate of incremental innovation but a substantial collapse in product variety, radical innovation and basic research".

- **Can the members give any practical or theoretical example to clarify this function?**

  UNICE answer:

  The link between innovation and product liability law is complex. Although the conclusion in the study that strict liability regimes would induce greater process innovation, an increased rate of incremental innovation but a substantial collapse in product variety, radical innovation and basic research, is theoretically plausible, actual experience of innovation is much more complex than this in practice. It is difficult to generalise experience here.

- **Do the members share the view that the keeping of the development risk clause does not compromise the attainment of satisfactory product innovation?**

  UNICE answer:

  UNICE considers that the keeping of the development risk clause is essential, and we do not believe that it compromises the attainment of satisfactory product innovation. The study has rightly identified that theoretical analysis concludes that removal of the DRC would produce a chilling effect on innovation. We consider that such an effect is also influenced by the access to justice and procedural factors mentioned above. Given that there are certain to be changes in the access to justice and procedural factors over coming years, and that such changes seem likely to produce adverse effects in any event, we consider that it would clearly be damaging to contemplate removal of the DRC in this uncertain climate.

  The development risks defence plays a role in ensuring that the Product Liability Directive strikes an appropriate balance between the interests of producers and the interests of consumers. The practical experience of claims under the Directive is still small, and as a result there is even less experience of the operation of the development risks defence.

  The existence of the defence is important for industries, particularly those involved in product innovation even though the practical experience is limited. As the use of the Product Liability Directive grows, it is to be expected that the role of the defence will become even more significant, as will its importance in maintaining a proper balance between the various interested affected by it.

  In UNICE's view, the Commission should not initiate any significant reforms at this stage but rather monitor ongoing developments.

3. Effects on market structure

The conclusions of the study also point to the fact that the removal of the development risk clause might bring about high fixed and sunk costs which could in turn result in more concentrated markets.

- **Do the members view this as a real possibility?**

UNICE answer:

It is difficult to predict whether the removal of the development risk defence would lead to significant changes in market structure. In the short term, removal of the defence may result in a decrease in innovation in some industries, which may ultimately have some impact on market concentration.

The effect would be magnified if the defence were removed, and this was followed over time by significant cases in which producers were held liable under the product liability laws for risks that would otherwise have been covered by the defence.

4. An EU-wide compensation fund?

Based on a survey of existing schemes available to consumers in different member States and the empirical observation that these schemes often result in asymmetry in consumer protection, one of the study's recommendations is to couple the maintenance of the clause with setting up an EU-wide compensation fund as an appropriate means for guaranteeing harmonised and adequate protection for all citizens. The study suggests that the fund should be of a mixed private-public nature.

- **Do the members have any experience to share on the functioning of national (sectoral) funds?**
- **Do they see any additional advantage in an EU-wide compensation fund?**
- **Could such a fund co-exist with existing national funds?**
- **What factors do they consider to be relevant in order to determine the private and/or public nature of this fund?**

UNICE answer:

We see little merit in such a fund. The likelihood of it being necessary is by definition low, and its potential scope is utterly unclear. It is therefore likely that an uncertain but possibly significant fund would simply be retained to no effect. There would be very considerable uncertainties over the practicalities: how much should each business or government or consumers pay? What circumstances should trigger payment, and how much? The administration costs for a fund to which every business in the EU should contribute would be hugely disproportionate. In the event that compensation should be necessary, in addition to existing and often extensive national provisions, for rare, unforeseeable, catastrophic cases, particular national arrangements would be likely to be devised to fit particular circumstances.

To the extent that such funds have been successful in any country, they have been established to deal with specific products or, in some cases, specific injuries. In these cases, it is possible to identify with at least some clarity the industries that ought to contribute, and the nature and extent of the risks/injuries are capable of some sort of assessment.

The examples cited in the Fondazione Roselli study clearly demonstrate that these kinds of solutions are practical only where very specific industries or risks are identified.

A special compensation fund, unless it is to be funded entirely by public finances, will be impractical because, in the absence of an ability to assess the nature, extent, or even the source of the risk, it will not be possible to effectively and fairly determine the basis upon which industries are to contribute to the fund. At best, it will be necessary to take a very broad-brush approach to the question, which is almost certain to produce serious inequities for businesses, inefficiencies which lead to higher prices for consumers, and a stifling of innovation even in respect of products that, in reality, deliver very low risks.

In certain sectors, the spontaneous/voluntary creation of private funds could be promoted (e.g. blood products in Italy).